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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,547	01/13/2006	Joachim Hoernes	21731 US	9151
23690 7590 02/22/2010 ROCHE DIAGNOSTICS OPERATIONS INC. 9115 Hague Road Indianapolis, IN 46250-0457				
EXAMINER				
TOTH, KAREN E				
ART UNIT		PAPER NUMBER		
3735				
NOTIFICATION DATE		DELIVERY MODE		
02/22/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/559,547

Applicant(s)

HOENES ET AL.

Examiner

KAREN E. TOTH

Art Unit

3735

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date 2/13/06

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Species B in the reply filed on 23 November 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 9 and 10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 23 November 2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Line 7 of claim 1 refers to "a second proximal end", but no first proximal end is ever defined. It appears that the claim is directed to first and second ends of an element, where the first end is distal and the second end is proximal. For the purposes of examination, the claim will be treated as though line 5 reads "a distal end" and line 7 reads "a proximal end".

Line 10 of claim 1 refers to "the region of the distal end". There is no antecedent basis for this limitation; for the purposes of examination it will be treated as though reading "a region of the distal end".

Line 12 of claim 1 refers to "the light guide". There is no antecedent basis for this limitation. It appears that Applicant intends to reference the light-conducting element set forth in line 5; for the purposes of examination it will be treated as such.

Line 2 of claim 6 refers to "a separate carrier", but it is not clear what this carrier is separate from. For the purposes of examination, the claim will be treated as though the test field is contained on a carrier that is separate from the light-conducting element referenced later in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, 11-14, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Coleman (US 4622974).

Regarding claim 1, Coleman discloses a system for analyzing a sample comprising a test field with a reagent which, on contact, interacts with an analyte contained in a sample resulting in an optically detectable change in the test field

(column 7, lines 53-68), a light-conducting element with a distal end arranged in a region of the test field (element 16 - figures 1 and 1a) and a proximal end into which light may be conducted (element 14) and which can conduct light away again from the test field (column 4, lines 42-66), and a lancet having a tip located in a region of the distal end and test field (element 19; figures 1, 1a) such that, during a lancing process, the lancet tip extends beyond the distal end of the light-conducting element and the test field (figure 1a). The Examiner notes that "in the region of" is non-limiting, and any two components of the same invention may be reasonably considered to be "in a/the region of" each other.

Regarding claim 4, since the test field (sample cavity 36) is defined by the end of the light-conducting element (optical fiber 16) (column 4, lines 32-35), they are inherently permanently connected.

Regarding claims 11-14, Coleman's light-conducting element is surrounded by and concentrically within the lancet, which is hollow (figure 1a).

Regarding claim 17, Coleman further discloses the system being optically contacted with an analytical unit of an analytical instrument such that light is coupled into or out of the light-conducting element (column 4, lines 42-66).

7. Claims 1-3, 5-8, and 16-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Garcia (US 4627445).

Regarding claim 1, Garcia discloses a system for analyzing a sample comprising a test field with a reagent (elements 94, 184) which, on contact, interacts with an

analyte contained in a sample resulting in an optically detectable change in the test field (column 7 line 14 to column 8 line 34), a light-conducting element with a distal end arranged in a region of the test field (elements 50, 172) and a proximal end into which light can be coupled to conduct the light to the test field (figure 4) and where light may be conducted away again from the field with the same (element 172) or another (element 52) light-conducting element, and a lancet having a lancet tip located in the region of the distal end of the element and test field (elements 90, 182), where the lancet tip extends beyond the distal end of the light-conducting element and the test field during a lancing process (figures 4, 6, 11). The Examiner notes that "in the region of" is non-limiting, and any two components of the same invention may be reasonably considered to be "in a/the region of" each other.

Regarding claim 2, Garcia further discloses the test field reacting essentially irreversibly with the analyte (column 7 line 14 to column 8 line 34).

Regarding claim 3, Garcia further discloses the system being suitable only for single use (column 2, lines 41-44; column 3, lines 53-58).

Regarding claim 5, Garcia further discloses the distal end of the light-conducting element being reversibly positioned at the test field such that it may be removed (figure 4 - when disposable probe package 12 is removed, test field 94 is removed from the light-conducting element 50).

Regarding claim 6, Garcia further discloses the test field (element 94) being positioned on a carrier (element 12) separate from and below the light conducting element (figure 4).

Regarding claims 7 and 8, Garcia further discloses a plurality of test fields and lancets (column 2, lines 41-44).

Regarding claim 16, Garcia further discloses the system being suitable for determining a glucose concentration from blood (abstract).

Regarding claim 17, Garcia further discloses the system being optically contacted with an analytical unit of an analytical instrument such that light is coupled into or out of the light-conducting element (column 5, lines 64-65; column 7, lines 2-10).

Regarding claim 18, Garcia further discloses the system being used in a lancing device (element 30 - figure 4).

Regarding claim 19, Garcia further discloses the system being optically contacted with an analytical unit of an analytical instrument such that light is coupled into or out of the light-conducting element (column 5, lines 64-65; column 7, lines 2-10).

Regarding claim 20, Garcia further discloses the lancing device (element 30) being coupled to an analytical unit (element 54) such that light may be coupled into the light-conducting element and light conducted away from the test field may be detected by the analytical unit (figure 4; column 7, lines 2-10).

Regarding claim 21, Garcia further discloses a drive unit for the lancet (column 6, lines 43-56).

Regarding claim 22, Garcia further discloses the lancing device (element 30) containing a drive unit for the light-conducting element (element 54).

Regarding claim 23, Garcia further discloses a drive unit for transporting the test element (element 46 causes movement of system 12 within the device - column 6 line 52 to column 7 line 2).

8. Claims 1, 3, 15, 17-19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Staehlin (US 5636640).

Regarding claim 1, Staehlin discloses a system for sample analysis comprising a test field with a reagent that interacts with an analyte in a sample to create an optically detectable change in the test field (element 20; column 4, lines 54-59); a light conducting element having a distal end that is arranged in a region of the test field (elements 13 and 41; figure 9) and a proximal end that may be coupled to a light source for delivery of light to the test field (element 41 may be remote, with delivery via element 13), another light-conducting element for conducting light away from the test field (element 42), a lancet with a lancet tip in the region of the distal end and test field (element 56), where the lancet tip extends beyond the distal end of the light-conducting element and the test field while lancing (figure 6b). The Examiner notes that "in the region of" is non-limiting, and any two components of the same invention may be reasonably considered to be "in a/the region of" each other.

Regarding claim 3, Staehlin discloses the system being suitable only for single use (column 1, lines 21-23).

Regarding claim 15, Staehlin further discloses the lancet tip being embedded in a sterile protection (before insertion the lancet tip is in a sterile assembly - column 1, lines 19-20 and figure 1).

Regarding claim 17, Staehlin further discloses the system being optically contacted with an analytical unit of an analytical instrument such that light is coupled into or out of the light-conducting element (column 1, lines 55-60).

Regarding claim 18, since the system lances, it is a lancing device.

Regarding claim 19, Staehlin further discloses the system being optically contacted with an analytical unit of an analytical instrument such that light is coupled into or out of the light-conducting element (column 1, lines 55-60).

Regarding claim 22, Staehlin further discloses a drive unit for the light-conducting element (elements 40, 47).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Garcia in view of Kuhr (US 7396334).

Garcia discloses all the elements of the claimed invention, as described above, except for the lancing device using the system having a magazine of systems. Kuhr

teaches a lancing device incorporating a plurality of systems comprising analytical test fields and lances into a magazine (claim 16; abstract), in order to combine all components of a system with disposable pieces into a single, easy-to-handle unit. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Garcia part of a magazine of such systems in a lancing device, as taught by Kuhr, in order to combine all components of a system with disposable pieces into a single, easy-to-handle unit.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2008/0249435 to Haar and 2007/0191696 to Mischler, which disclose similar inventions.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735